SPECIFICATION

Gasket for Pre-Filled Syringe and Pre-Filled Syringe

Field of the Invention

The present invention relates to a gasket for a pre-filled syringe and the pre-filled syringe.

Background Art

In generally, chemical liquid is charged into a syringe barrel when it is used. In recent years, a pre-filled syringe in which chemical liquid is previously charged into the syringe barrel has been developed, and working load in medical site is reduced. Recently, a pre-filled syringe in which contrast medium is charged into the syringe is also used. Since the contrast medium has relatively high viscosity, it is considered that it is important to increase sliding ability of a gasket so as to reduce the charging pressure. Especially when a syringe barrel is made of polymeric resin, since the sliding ability of the gasket is inferior, silicon oil is applied onto a peripheral side surface of a gasket that is in contact with an inner surface of the syringe barrel to enhance the sliding ability, or polyethylene fluoride resin such as Teflon (registered trade name) is laminated. However, if silicon applied to a gasket is mixed into chemical liquid, it becomes foreign matter, this may cause product defect, and there is apprehension that such foreign matter may have toxicity to human body.

It is normal that the pre-filled syringe is sterilized after chemical liquid is charged or chemical liquid is charged in axenic conditions. Sterilization after charging is carried by heating the pre-filled syringe for

example, but it is important to form the gasket into such a shape that high pressure chemical liquid caused by heat at the time of sterilization is not leaked. When polyethylene fluoride resin or the like is laminated on a gasket, since the polyethylene fluoride resin is hard, if the gasket is inserted into the syringe barrel, fine wrinkles may be generated on a peripheral side surface of the gasket, and chemical liquid may be leaked through the wrinkles at the time of sterilization.

The present inventor studies hard to solve these problems and as a result, the inventor invented the following inventions.

Summary of the Invention

According to claim 1, there is provided a gasket used for a pre-filled syringe into which liquid is charged, wherein a peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel is provided with a restriction, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered shape.

In this gasket of claim 1, as described in claim 2, it is preferable that hardness of the gasket is 55 to 60 when the hardness is measured by a JIS hardness meter. Further, as described in claim 3, it is preferable that the peripheral side surface that is in contact with the inner surface of the syringe barrel and/or a bottom surface that is in contact with liquid is laminated with polyethylene fluoride resin.

According to claim 4, there is provided a pre-filled syringe into which liquid is charged and tightly closed with the gasket described in any one of claims 1 to 3.

In this pre-filled syringe of claim 4, the liquid is, for example,

contrast medium as described in claim 5.

In the gasket of claims 1 to 3 and the pre-filled syringe of claims 4 and 5, the gasket plays a role as a lid for tightly closing the liquid charged into the syringe barrel, and also plays a role as a piston when the pre-filled syringe is used. As the JIS hardness meter for measuring the hardness of the gasket, "Durometer" produced by Shimazu Seisakusho can be used for example. A preferable range of the hardness of the gasket measured by the JIS hardness meter is 57 to 59. Material of the gasket is not limited only if it has appropriate hardness, but usually, the material is normal butyl rubber, silicon rubber or polymeric resin, and more preferably, chlorinated butyle rubber.

The peripheral side surface that is in contact with the syringe barrel or the bottom surface that is in contact with liquid can be laminated with polyethylene fluoride resin using a conventionally known laminating method. Silicon may be applied to the peripheral side surface of the gasket that is in contact with the inner surface of the syringe barrel, but it is preferable that silicon is not applied to the bottom syringe that is in contact with the liquid charged into the syringe barrel. The silicon can also be applied by a conventionally known application method.

Material of the syringe barrel is not limited, and any of glass and resin can be used. Especially, resin is preferable, and example of the material is annular polyolefin fiber.

Liquid to be charged into the syringe barrel is not limited to the contrast medium, and liquid other than the contrast medium may be used. Example of contrast medium is iomeprole. An amount of liquid to be charged into the syringe barrel is usually about 10 to 200 ml, and

more preferably 50 to 100 ml.

Brief Description of the Drawings

Fig.1 is a sectional view of a pre-filled syringe according to an embodiment of the present invention; and

Fig.2 is a side view of a gasket according to the embodiment of the invention.

Detailed Description of the Preferred Embodiments

A preferred embodiment of the present invention will be explained with reference to the accompanying drawings below.

As shown in Fig.1, in a pre-filled syringe 1 of this embodiment, a contrast medium 3 as one example of chemical liquid is charged in a cylindrical syringe barrel 2. The syringe barrel 2 is made of annular polyolefin fiber for example. The syringe barrel 2 is provided at its tip end (left end of the syringe barrel 2 in Fig.1) with a nozzle 4. The nozzle 4 is formed with a lure lock 5, and by mounting a cap 6 on the lure lock 5, the nozzle 4 is tightly closed. A columnar gasket 7 is inserted into the syringe barrel 2 from an opened rear end (right end of the syringe barrel 2 in Fig.1) of the syringe barrel 2, and the contrast medium 3 in the syringe barrel 2 is tightly closed by the gasket 7.

The gasket 7 is made of chlorinated butyle rubber for example, and the gasket 7 preferably has hardness of 55 to 60 degrees, more preferably 57 to 59 degrees when the hardness is measured using JIS hardness meter. As shown in Fig.2, a peripheral side surface 7a of the gasket 7 that is in contact with an inner surface of the syringe barrel 2 is formed with an annular restriction 8. A depth a of the restriction 8 is

about 0.05 to 1.0 mm, and more preferably, 0.1 to 0.5 mm if the gasket has a diameter b of 30 to 35 mm and a height c of 15 to 18 mm.

A bottom surface 7b (lower surface of the gasket 7 in Fig.2) that is in contact with the contrast medium 3 charged into the syringe barrel 2 is formed into a conical surface. The bottom surface 7b and the peripheral side surface 7a are laminated with polyethylene fluoride resin.

A central portion of a bottom surface 7c (upper surface of the gasket 7 in Fig.2) that is not in contact with the contrast medium 3 charged into the syringe barrel 2 is formed, as shown in Fig.2, with a threaded hole 9 into which a rod is fitted. As shown in Fig.2, a periphery of the bottom surface 7c is formed into a tapered slant 10. A range (range of the gasket 7 from an outer diameter in its diametrical direction) d where the slant 10 is formed is about 0.5 to 5 mm, and more preferably about 1 to 3 mm if the gasket has a diameter b of 30 to 35 mm and a height c of 15 to 18 mm.

According to this pre-filled syringe 1 having the above-described structure, the cap 6 is removed from the nozzle 4, and a tip end of an extension tube (not shown) for example is threadedly fitted to the lure lock 5. A rod (not shown) is fitted to the bottom surface 7c of the gasket 7. Then, the rod is pushed to push out the contrast medium 3 in the syringe barrel 2 through the extension tube, thereby charging the contrast medium 3 into a target position.

Industrial Applicability

According to the inventions of claims 1 to 5, the sliding ability when polyolefin resin is used as material of a syringe barrel is used is

remarkably enhanced, and liquid is not leaked almost at all when the pre-filled syringe is sterilized. The gasket can smoothly move at the time of sterilization even when the gasket is pushed out, and there is no adverse possibility that the gasket is diagonally inclined with respect to a center axis of the syringe barrel.